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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,243	04/24/2001	Krzysztof Masternak	010830-117	3494

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/840,243	Applicant(s) MASTERNAK ET AL.	
	Examiner Amy M. DeCloux	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 62-66, drawn to a protein capable of restoring MHC-II expression, classified in class 530, subclass 350.

II. Claims 7-10, drawn to an antibody specifically recognizing a protein of claim 1, classified in class 530, subclass 387.1.

III. Claims 11-18, 20 and 67-68 drawn to a nucleic acid molecule encoding a protein of claim 1, and a vector thereof, classified in class 536, subclass 23.1.

IV. Claim 19, drawn to a ribozyme comprising the nucleic acid molecule of claim 13, classified in class 536, subclass 24.5.

V. Claims 21-30, drawn to a process for identifying inhibitors comprising measuring function or activity, classified in class 435, subclass 7.24.

VI. Claims 31-36 and 72, drawn to a process for identifying inhibitors comprising detection or measuring a product which contributes to the synthesis of said protein or peptide, classified in class 435, subclass 7.24.

VII. Claims 37-38, drawn to a process for identifying inhibitors comprising designing said inhibitors on the basis of the three dimensional structure of a protein or a peptide of claim 1, classified in class 435, subclass 7.24.

VIII. Claims 39-49, drawn to a process for identifying inhibitors comprising a DNA fragment of the MHC class II promoter, classified in class 436, subclass 6.

IX. Claims 50-52 and 56, drawn to an inhibitor identified by the process of claim 21, and pharmaceutical composition thereof, classified in class 530, subclass 350.

X. Claim 53, drawn to an inhibitor of a protein of claim 21, classified in class 530, subclass 350.

XI. Claim 54, drawn to a nucleic acid molecule encoding an inhibitor of claim 50, classified in class 536, subclass 23.1.

XII. Claims 55 and 58, drawn to a method of using the inhibitor of claim 50 comprising administering said inhibitor, classified in class 424, subclass 184.1.

XIII. Claim 57, drawn to a method of using an inhibitor of claim 50 for the preparation of a medicant, classified in class 514, subclass 2.

XIV. Claims 59-60, drawn to a protein complex comprising cellular proteins capable of binding to the W-X-X2-Y box of MHC-class II promoters and CIITA, classified in class 424, subclass 193.1.

XV. Claim 61, drawn to an antibody capable of recognizing a protein complex of claim 59, classified in class 530, subclass 387.1.

XVI. Claims 69 and 71, drawn to a process for identifying inhibitors which have the capacity to inhibit a function or an activity of a nucleic acid molecule of claim 11

comprising detecting or measuring said function or activity, classified in class 435, subclass 6.

XVII. Claims 70 and 73, drawn to a process for identifying inhibitors which have the capacity to inhibit the synthesis of a nucleic acid molecule of claim 11, comprising detecting or measuring said function or activity, classified in class 435, subclass 6.

XVIII. Claim 74, drawn to a process of screening which comprises screening for the binding of molecules to the nucleic acid molecule of claim 11, classified in class 435, subclass 6.

XIX. Claim 75, drawn to a process for identifying inhibitors which have the capacity to inhibit a nucleic acid comprising designing said inhibitors on the basis of the three dimensional structure of the protein of Claim 1, classified in class 435, subclass 6.

XX. Claim 76, drawn to an inhibitor of a nucleic acid molecule, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, III, IV, IX, X, XI, XIV, XV and XX are unique products. They encompass nucleic acid molecules, proteins and antibodies, each having a distinct structure, said distinct structure conferring to each product a distinct set of biochemical properties. Therefore, Groups I, II, III, IV, IX, X, XI, XIV, XV and XX are patentably distinct.

Groups V-VIII, XII-XIII and XVI-XIX are unique methods. The endpoints of Groups V/VII/VIII/XVI/XVII/XIX, XVIII, XII and XIII are distinct. Though the endpoints of Groups V, VII, VIII, XVI, XVII and XIX are the same, each group uses a distinct combination of process steps and ingredients. Therefore, Groups V-VIII, XII-XIII and XVI-XIX are patentably distinct each from the other.

Groups IX and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the inhibitor can be used as an immunogen in a method of making antibody secreting hybridomas, as well as an inhibitor of a protein of Claim 1.

Groups IX and V are related as product and process of use as are Groups X and V. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the inhibitor, can be used as an immunogen in a method of making antibody secreting hybridomas, as well as an inhibitor of a protein of Claim 1.

Groups IX and XII are related as product and process of use as are Groups IX and XIII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the inhibitor, can be used as an immunogen in a method of making antibody secreting hybridomas, as well as in a method for the preparation of a medicant, or in a method comprising administering said inhibitor to a patient.

Groups III and XVI are related as product and process of use as are Groups III and XVII, as are Groups III and XIX. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the nucleic acid molecule encoding protein of claim 1, can be used as an immunogen in a method of making antibody secreting hybridomas, as well as in a method for identifying inhibitors.

Groups III and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the nucleic acid molecule encoding protein of claim 1, can be used as an immunogen in a method of making antibody secreting hybridomas, as well as in a process of screening which comprises screening for the binding of molecules to the nucleic acid of claim 11.

Groups I and V are related as product and process of use as are Groups I and VI, as are Groups I and VII, as are Groups I and VIII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the protein of claim 1, can be used as an immunogen in a method of making antibody secreting hybridomas, as well as in a method for identifying inhibitors .

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
September 30, 2002

Patrick J. Nolan, Ph.D.
Primary Patent Examiner
Group 1640